



N THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Robert MARTUZA et al

Title:

REPLICATION-COMPETENT HERPES SIMPLEX

VIRUS MEDIATES DESTRUCTION OF NEOPLASTIC

CELLS

Appl. No.:

10/748,233

Filing Date:

12/31/2003

Examiner:

Not yet assigned

Art Unit:

1632

## UNDER 37 CFR §1.56

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

## TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the foreign search report.

## RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date

FOLEY & LARDNER LLP

Customer Number: 22428

Telephone:

(202) 672-5404

Facsimile:

(202) 672-5399

Stephen A. Bent Attorney for Applicant

Registration No. 29,768

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Substitute for form 1449B/PTO				Complete if Known		
	INFORMATI	ON DISCLOS	URE	) , , <sub>E</sub>	Application Number	10/748,233	
	STATEMEN	T BY APPLIC	ANT		(Sing Date	12/31/2003	
	Data Submit	Hadi lulu 22 1	od, .	IUL 2 3 2004	শিক্ষ Named Inventor	Robert MARTUZA	
	Date Submit	tted: July 23,	20 <b>4</b> 1	IUL Z	G∰up Art Unit	1632	
	(use as many s	sheets as nec	essa <b>rs</b> )		*aminer Name	Not yet assigned	
Sheet	1	of	1	TRADEMAS	Attorney Docket Number	066683-196	

U.S. PATENT DOCUMENTS							
Examiner	Cite No.1	U.S. Patent Document		Name of Patentee or Applicant of	Date of Publication of	Pages, Columns, Lines, Where Relevant	
Initials*		Number	Kind Code <sup>2</sup> (if known)	Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear	
					<del></del>		

			FOREIGN PATENT DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Office <sup>3</sup> Number <sup>4</sup> Kind Code (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	A1	WO 92/03563	CENTRAAL DIERGENEESKUNDIG INSTITUUT	3/5/1992		
	A2	WO 96/39841	GEORGETOWN UNIVERSITY	12/19/1996		
						1

Examiner Initials*  Cite No.1  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.  A3 International Search Report  A4 Klaus ROEMER et al., "Transduction of foreign regulatory sequences by a replication-defective herpes simplex virus type 1: The rat neuron-specific enolase promoter", Virus Research 35 (1995) pp. 81-89.  A5 Shin-ichi MIYATAKE et al., "Transcriptional Targeting of Herpes Simplex Virus for Cell-Specific Replication", Journal of Virology, Vol. 71, No. 7, July 1997, pp. 5124-5132.  A6 R.G. VILE et al., "Targeting of cytokine gene expression to malignant melanoma cells using tissue specific promoter sequences", Annals of Oncology 5 (Suppl. 4), S59-S65, 1994.  A7 C.A. KEECH et al., "Analysis of Rat Prolactin Promoter Sequences that Mediate Pituitary-Specific and 3', 5'-Cyclic Adenosine Monophosphate-Regulated Gene Expression in Vivo", Vol. 3, No. 5, Mol. Endo. 1989, pp. 832-839.  Christophe LEFEVRE et al., "Tissue-specific expression of the human growth hormone gene is conferred in part by the binding of a specific <i>trans</i> -acting factor", The EMBO Journal, vol. 6, no. 4, pp. 971-981, 1987.  A9 Shigeki KURIYAMA et al., "A Potential Approach for Gene Therapy Targeting Hepatoma Using a Liver-Specific Promoter on a Retroviral Vector", Cell Structure and Function, 16: (1991) pp. 503-510.  A10 Richard G. VILE et al., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells", Cancer Research, 53 pp. 962-967, 1993			NON PATENT LITERATURE DOCUMENTS	·
Klaus ROEMER et al., "Transduction of foreign regulatory sequences by a replication-defective herpes simplex virus type 1: The rat neuron-specific enolase promoter", Virus Research 35 (1995) pp. 81-89.  A5 Shin-ichi MIYATAKE et al., "Transcriptional Targeting of Herpes Simplex Virus for Cell-Specific Replication", Journal of Virology, Vol. 71, No. 7, July 1997, pp. 5124-5132.  A6 R.G. VILE et al., "Targeting of cytokine gene expression to malignant melanoma cells using tissue specific promoter sequences", Annals of Oncology 5 (Suppl. 4), S59-S65, 1994.  A7 C.A. KEECH et al, "Analysis of Rat Prolactin Promoter Sequences that Mediate Pituitary-Specific and 3', 5'-Cyclic Adenosine Monophosphate-Regulated Gene Expression in Vivo", Vol. 3, No. 5, Mol. Endo. 1989, pp. 832-839.  A8 Christophe LEFEVRE et al., "Tissue-specific expression of the human growth hormone gene is conferred in part by the binding of a specific trans-acting factor", The EMBO Journal, vol. 6, no. 4, pp. 971-981, 1987.  A9 Shigeki KURIYAMA et al., "A Potential Approach for Gene Therapy Targeting Hepatoma Using a Liver-Specific Promoter on a Retroviral Vector", Cell Structure and Function, 16: (1991) pp. 503-510.  A10 Richard G. VILE et al., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells", Cancer Research,			item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher,	Τ <sup>6</sup>
virus type 1: The rat neuron-specific enolase promoter", Virus Research 35 (1995) pp. 81-89.  Shin-ichi MIYATAKE et al., "Transcriptional Targeting of Herpes Simplex Virus for Cell-Specific Replication", Journal of Virology, Vol. 71, No. 7, July 1997, pp. 5124-5132.  R.G. VILE et al., "Targeting of cytokine gene expression to malignant melanoma cells using tissue specific promoter sequences", Annals of Oncology 5 (Suppl. 4), S59-S65, 1994.  A7 C.A. KEECH et al, "Analysis of Rat Prolactin Promoter Sequences that Mediate Pituitary-Specific and 3', 5'-Cyclic Adenosine Monophosphate-Regulated Gene Expression in Vivo", Vol. 3, No. 5, Mol. Endo. 1989, pp. 832-839.  A8 Christophe LEFEVRE et al., "Tissue-specific expression of the human growth hormone gene is conferred in part by the binding of a specific <i>trans</i> -acting factor", The EMBO Journal, vol. 6, no. 4, pp. 971-981, 1987.  A9 Shigeki KURIYAMA et al., "A Potential Approach for Gene Therapy Targeting Hepatoma Using a Liver-Specific Promoter on a Retroviral Vector", Cell Structure and Function, 16: (1991) pp. 503-510.  A10 Richard G. VILE et al., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells", Cancer Research,		A3	International Search Report	
Journal of Virology, Vol. 71, No. 7, July 1997, pp. 5124-5132.  A6  R.G. VILE et al., "Targeting of cytokine gene expression to malignant melanoma cells using tissue specific promoter sequences", Annals of Oncology 5 (Suppl. 4), S59-S65, 1994.  A7  C.A. KEECH et al, "Analysis of Rat Prolactin Promoter Sequences that Mediate Pituitary-Specific and 3', 5'-Cyclic Adenosine Monophosphate-Regulated Gene Expression in Vivo", Vol. 3, No. 5, Mol. Endo. 1989, pp. 832-839.  A8  Christophe LEFEVRE et al., "Tissue-specific expression of the human growth hormone gene is conferred in part by the binding of a specific trans-acting factor", The EMBO Journal, vol. 6, no. 4, pp. 971-981, 1987.  A9  Shigeki KURIYAMA et al., "A Potential Approach for Gene Therapy Targeting Hepatoma Using a Liver-Specific Promoter on a Retroviral Vector", Cell Structure and Function, 16: (1991) pp. 503-510.  A10  Richard G. VILE et al., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells", Cancer Research,		A4		
promoter sequences", Annals of Oncology 5 (Suppl. 4), S59-S65, 1994.  A7 C.A. KEECH et al, "Analysis of Rat Prolactin Promoter Sequences that Mediate Pituitary-Specific and 3', 5'-Cyclic Adenosine Monophosphate-Regulated Gene Expression in Vivo", Vol. 3, No. 5, Mol. Endo. 1989, pp. 832-839.  A8 Christophe LEFEVRE et al., "Tissue-specific expression of the human growth hormone gene is conferred in part by the binding of a specific trans-acting factor", The EMBO Journal, vol. 6, no. 4, pp. 971-981, 1987.  A9 Shigeki KURIYAMA et al., "A Potential Approach for Gene Therapy Targeting Hepatoma Using a Liver-Specific Promoter on a Retroviral Vector", Cell Structure and Function, 16: (1991) pp. 503-510.  A10 Richard G. VILE et al., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells", Cancer Research,		A5		
Adenosine Monophosphate-Regulated Gene Expression in Vivo", Vol. 3, No. 5, Mol. Endo. 1989, pp. 832-839.  A8 Christophe LEFEVRE et al., "Tissue-specific expression of the human growth hormone gene is conferred in part by the binding of a specific <i>trans</i> -acting factor", The EMBO Journal, vol. 6, no. 4, pp. 971-981, 1987.  A9 Shigeki KURIYAMA et al., "A Potential Approach for Gene Therapy Targeting Hepatoma Using a Liver-Specific Promoter on a Retroviral Vector", Cell Structure and Function, 16: (1991) pp. 503-510.  A10 Richard G. VILE et al., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells", Cancer Research,		A6		
by the binding of a specific <i>trans</i> -acting factor", The EMBO Journal, vol. 6, no. 4, pp. 971-981, 1987.  A9 Shigeki KURIYAMA et al., "A Potential Approach for Gene Therapy Targeting Hepatoma Using a Liver-Specific Promoter on a Retroviral Vector", Cell Structure and Function, 16: (1991) pp. 503-510.  A10 Richard G. VILE et al., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells", Cancer Research,		A7		
Promoter on a Retroviral Vector", Cell Structure and Function, 16: (1991) pp. 503-510.  A10 Richard G. VILE et al., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells", Cancer Research,		A8		
	<del></del>	A9		
00, pp. 002-007, 1000.		A10	Richard G. VILE et al., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells", Cancer Research, 53, pp. 962-967, 1993.	
A11 Y. MIYAO et al., "Selective expression of foreign genes in glioma cells: use of the mouse myelin basic protein gene promoter to direct toxic gene expression", Journal of Neuroscience Research, vol. 36, 1993, pp. 472-479.		A11		

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.